

REMARKS

In the Office Action dated September 22, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following five separate and distinct inventions:

- Group I. Claims 1-6, drawn to antisense nucleic acids and methods, classified in class 536, subclass 24.5.
- Group II. Claims 7-12, drawn to ribozymes and methods, classified in class 435, subclass 91.31.
- Group III. Claims 13-14, drawn to methods of identifying modifiers of F11 receptor function, classified in class 435, subclass 7.21.
- Group IV. Claims 15, 16, 19, 20, drawn to methods of obtaining and detecting DNA, classified in class 435, subclass 6.
- Group V. Claims 17 and 18, drawn to polynucleotides encoding a F11 receptor, classified in class 536, subclass 23.5.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter Group V, Claims 17 and 18, drawn to polynucleotides encoding a F11 receptor, classified in class 536, subclass 23.5. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, Applicants submit that the present invention recognizes that a stimulatory monoclonal antibody (termed M.Ab.F11) induces aggregation and granule secretion of human platelets through its specific binding to F11 receptor. The present invention provides an isolated nucleic acid molecule encoding a human platelet F11 receptor. The invention also provides an antisense nucleic acid molecule complementary to at least a portion of the mRNA encoding the human platelet F11 receptor. The isolated nucleic acid molecules of the present invention can be inserted into suitable expression vectors and/or host cells. Expression of the nucleic acid molecules encoding the human platelet F11 receptor results in production of human platelet F11 receptor in a host cell. Expression of the antisense nucleic acid molecules in a host cell results in decreased expression of the human platelet F11 receptor. The present invention further provides a ribozyme having a recognition sequence complementary to a portion of mRNA encoding a human platelet F11 receptor. Thus, the ribozyme can be introduced into a cell to also achieve decreased expression of human platelet F11 receptor in the cell. The invention also provides a method of screening a substance for the ability of the substance to modify F11 receptor function, and a method of obtaining DNA encoding a human platelet F11 receptor. The present invention further provides a DNA oligomer capable of hybridizing to a nucleic acid molecule encoding a human platelet F11 receptor. The DNA oligomer can be used in a method

of detecting presence of a human platelet F11 receptor in a sample, which method is also provided by the present invention.

The Examiner acknowledges that Groups I, II and V are directed to related products. However, relying on MPEP § 806.05 (j), the Examiner contends that Groups I, II and V are distinct inventions, because the antisense molecules of Group I are distinct from the rebozymes of Group II in physical structure and functional effect. The Examiner asserts that the antisense molecules and ribozymes are distinct from the polynucleotides of Group V because they have different sequences and opposite functions. Furthermore, the Examiner asserts that the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Applicants respectfully submit that in view of the discussion above regarding the concept of the present invention, the products Groups I, II and V all employ the same concept as recognized by the present invention. Therefore, Groups I, II and V are related to each other as different aspects of a single invention, and are not "independent and distinct."

The Examiner alleges that Groups III and IV are directed to methods that are distinct both physically and functionally, and are not required one for the other. The Examiner alleges that Group III requires methods of detecting the function of an F11 receptor, which is not required by Group IV. The Examiner asserts that Group IV requires methods of obtaining DNA, which is not required by Group III.

Applicants respectfully submit that the method of Groups III employs DNA sequences encoding F11R which can be obtained and detected by method of Group IV. The method of Group IV can be used for detecting F11R in the method of Group III. Accordingly, Groups III

and IV employ the same concept and are related to each other as different aspects of a single invention.

The Examiner acknowledges that the antisense molecules of Group I are related to the methods of Groups III and IV as product and process of use. However, the Examiner alleges that the antisense molecules of Group I are distinct from each of the methods of Groups III and IV. The Examiner alleges that the antisense molecules can be used in ways that are materially and functionally different than each of the methods because each of the methods of Groups III and IV are materially and functionally distinct from each other.

The Examiner acknowledges that the ribozymes of Group II are related to the method of Group IV as product and process of use. However, the Examiner alleges that the method of Group IV can be practiced with another materially different product such as the antisense molecules of Group I.

The Examiner acknowledges that the polynucleotides of Group V are related to the methods of Groups III and IV as product and process of use. However, the Examiner alleges that the polynucleotides of Group V are patentably distinct from each of the methods of Groups III and IV. The Examiner alleges that the polynucleotides can be used in ways that are materially and functionally different than each of the methods because Groups III and IV are materially and functionally distinct from each other.

Applicants submit that the products of Group I are antisense nucleic acid molecules complementary to mRNA of F11R sequences and are clearly prepared for the purpose of practicing the methods of Groups III (identifying modifiers of F11R function) and IV (detection of F11R). Similarly, ribozymes of Group II are complementary to a portion of mRNA encoding a human platelet F11 receptor and are clearly prepared for the purpose of practicing the methods

of Groups I; the polynucleotides of Group V are coding sequences F11R and are clearly prepared for the purpose of practicing the methods of Groups III and IV. Additionally, as discussed above, Groups III and IV are related. Accordingly, Groups II and IV are related and Groups V and III and IV are related.

Therefore, Groups I-V are related to each other as different aspects of a single invention, and are not "independent and distinct."

Applicants respectfully submit that the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and

subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal

challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the defined five groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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